REMARKS/ARGUMENTS

Rejections Under 35 U.S.C. §103

Claims 104 and 109-121 are rejected under 35 U.S.C. §103 as being unpatentable over Wan et al. (U.S. Patent No. 5,837,529) in combination with Kasai (J. Chromatography 618:203 (1993)) and Bussey et al. (U.S. Patent No. 6,011,148). The rejection is respectfully traversed.

Claim 104 is drawn to a method of purifying gram quantities of plasmid DNA from a cell, comprising the steps of lysing bacterial cells, removing contaminants from the lysate solution by precipitation, and recovering plasmid DNA from the supernatant using column chromatography over a tentacle anion exchange resin. Claim 115 is drawn to a method for removing contaminants from a plasmid DNA solution comprising the steps of contacting a solution comprising plasmid DNA with a tentacle anion exchange resin, the solution having a conductivity at which the plasmid DNA is bound to the resin, washing the resin to elute the contaminates, and eluting the plasmid DNA with a step or continuous gradient of increasing conductivity. As such both independent claims are limited by use of tentacle anion exchange resins. Dependent claims 109 – 113 and 119 are further limited to use of tentacle anion exchange resins having TMAE functional groups. Only dependent claims 114 and 121 have limitations to hydrophobic interaction chromatography.

Wan et al. teach a method of lysing cells comprising simultaneously flowing a cell suspension and a lysis solution through a static mixer. *See* Abstract. The Examiner acknowledges that Wan et al. do not teach the use of either anion exchange or hydrophobic interaction columns in the purification of plasmid DNA. Kasai reviews chromatographic procedures used for size-dependent fractionation of nucleic acids including ion exchange and hydrophobic interaction chromotography. *See* Abstract. The Examiner contends that Kasai bridges the nexus between the prior art and the instant claims by teaching the use of anion exchange and hydrophobic interaction columns in the separation of nucleic acid. The Examiner then asserts that the use of tentacle anion exchange chromatography in plasmid DNA separation was taught by Bussey et al. Applicant respectfully traverses.

As a first point, Bussey is not prior art to the present invention. Bussey was filed on August 1, 1996, whereas the instant application claims the priority of a provisional application filed July 19, 1996. The use of both tentacle anion exchange resin and hydrophobic interaction chromatography in the purification of plasmid DNA was disclosed in the provisional application from which priority is claimed in the present case, for example, see page 19, line 17 to page 21, line 19. Hence, Applicant submits that Bussey is not a valid prior art reference because it was filed after the priority date of the instant application.

Secondly, Applicant points out that the claims of the present application are limited to tentacle anion exchange chromatography which is neither taught nor suggested by Kasai. Furthermore, as to dependent claims 114 and 121, which further claim the use of hydrophobic interaction chromatography as an additional step, it is respectfully but strongly submitted that Kasai does not teach the use of hydrophobic interaction columns in the separation of plasmid DNA. Kasai teaches that chromatographic method based on hydrophobic interaction are more suitable for fractionation of tRNA, not plasmid DNA (page 209, right column, first paragraph), and concludes that hydrophobic interaction is unlikely to become popular, even in the fractionation of nucleic acids generally. *See* Abstract. Hence, Kasai neither teaches nor provides any motivation to one of ordinary skill in the art to use hydrophobic interaction columns in the separation of nucleic acid.

Moreover, Applicant submits that Kasai teaches away from the invention claimed in claim 114 because Kasai only teaches laboratory-based method, not large scale DNA purification as claimed herein. It is generally recognized by one of ordinary skill in the art that methods of small scale preparation performed in the laboratory are not suitable for large scale high throughput purification processes (instant specification, paragraph 10). Kasai only teaches molecular biology-based laboratory techniques. Kasai does not teach or suggest any method applicable to large scale DNA purification, which is outside the scope and focus of the Kasai review. Absent any teaching that addresses the technical difficulties encountered in large scale high throughput nucleic acid purification, Applicant submits that Kasai does not teach the method of claim 114.

Conclusion

For the reasons stated herein, Applicant respectfully requests that the rejection of claims 104 and 115, and claims dependent therefrom, under 35 U.S.C. §103 be withdrawn. Applicant submits that independent claim 104 and 115 are allowable and that the dependent claims are, in turn, also allowable. Should the Examiner have any questions, please do not hesitate to call Applicant's attorney at 832-446-2421.

Respectfully submitted,

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